



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,030	10/24/2003	Matthias H. Kraus	14014.0306U2	2346
36339 7590 12/24/2008 NATIONAL INSTITUTE OF HEALTH C/O Ballard Spahr Andrews & Ingersoll, LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER GODDARD, LAURA B	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 12/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

Address : COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10693030	10/24/2003	KRAUS ET AL.	14014.0306U2

EXAMINER

LAURA B. GODDARD

ART UNIT	PAPER
----------	-------

1642 5

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

1. The Amendment filed October 14, 2008 in response to the Office Action of June 11, 2008, is acknowledged and has been entered. Claims 35-42 remain withdrawn. Claims 43, 45, 46, 51-59 are currently being examined.
2. Previously pending claims 43, 46, and 51 have been amended. Claims 43, 45, 46, and 51-59 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions for the reasons set forth below.
3. The claims as currently constituted are directed to a "method of determining the level of expression of erbB3" which is a distinct method that differs in objective, method steps, response variables, populations, as well as criteria for success from the method originally presented which is directed to a "method of classifying a cancer as being correlated with a greater amount of expression of an erbB3 gene as compared to a control". The method originally presented and examined comprises assaying a sample from a subject already diagnosed with cancer, measuring and comparing levels of erbB3 expression in the sample with levels in a sample from a control subject, and classifying the cancer as being correlated with greater amounts of erbB3 expression when the level of expression in the cancer subject sample is higher relative to the control subject sample. The newly amended claims are drawn to a method that is not an obvious variant of the originally presented claims and is distinct. The newly amended claims are drawn to a method comprising measuring the level of erbB3 expression in any sample wherein overexpression is correlated with human malignancy. The amended claims differ in objective because they do not classify a cancer as being correlated with a greater amount of erbB3 expression compared to a subject sample expression level. The methods differ in steps, response variables, and populations assayed: the originally presented claims require assaying samples from subjects that are already diagnosed with cancer and classifying the cancer by expression level, wherein the amended claims are drawn to assaying any sample from any source, not necessarily a subject, and the sample assayed is not required to be from a subject already diagnosed with cancer. The amended claims differ in criteria for success because unlike the originally presented claims, no comparison is made between subject samples, no sample from a subject already diagnosed with cancer is assayed, and no cancer is being classified as being correlated with a greater amount of erbB3 expression compared to a subject control sample. The amended claims encompass samples that may be from subjects not diagnosed with cancer, which is a population outside the scope of the originally presented claims. The criteria of success for the originally presented claims was based on a higher level of erbB3 expression in cancer subject samples compared to control subject samples. The criteria for success for the amended claims is based on simply determining the level of expression in any sample. The correlation of erbB3 overexpression in any sample to a human malignancy is not an obvious variation of classifying a previously diagnosed cancer as having greater amounts of erbB3 expression compared to a control subject sample. This is clearly a different method effect. Finally, given the different objectives, method steps, response variables, populations and criteria for success, the two distinct inventions may raise different issues under 35 USC 112 1st paragraph.

4. Applicants argue that the objectives of the amended claims do not differ from the examined claims because they are both drawn to correlating cancer with erbB3 expression levels; the method steps are nearly identical because they are both drawn to measuring the level of expression of erbB3; the response variables are identical because the level of erbB3 expression is determined in both; the criteria for success is the same because both are based in the expression of erbB3 and its detection; and determining level of expression of erbB3 is an obvious variant of classifying cancer by determining expression of erbB3 in a sample. Applicants argue the only difference between the amended and examined claims is that in the amended claims, the level of expression is not compared to a control (p. 6-7).

Applicants' arguments were considered but were not found persuasive. The amended claims and originally presented claims differ in objectives, method steps, response variables, populations, and criteria for success for the reasons set forth above. The claims are not obvious variants for the reasons set forth above. The amended and original claims do not have the same effect. Classifying previously diagnosed cancer in a subject as having greater erbB3 expression is not the same effect as determining the level of expression of erbB3 and correlating erbB3 overexpression with human malignancy.

5. Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43, 45, 46, and 51-59 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R., 1.142(b) and M.P.E.P., 821.03.

6. The amendment filed October 14, 2008 amending all of the claims to an invention not originally presented is nonresponsive (see MPEP 821.03). The remaining claims are not readable on the originally presented invention for the reasons set forth above. Applicant is given a ONE MONTH time limit or until the expiration of the response period set in the last Office action, whichever is longer, to complete the response. NO EXTENSION OF THIS TIME LIMIT WILL BE GRANTED UNDER EITHER 37 CAR 1.136(a) OR (b) but the period for response set in the last office action may be extended up to a maximum of SIX MONTHS.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Laura B Goddard/
Examiner, Art Unit 1642